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No. 01-344

In the Supreme Court of the United States

TOMMY G. THOMPSON, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

Petitioners,

v.

WESTERN STATES MEDICAL CENTER, ET AL.

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF AMICUS CURIAE OF NATIONAL COMMUNITY PHARMACISTS ASSOCIATION IN SUPPORT OF RESPONDENTS

JOHN M. RECTOR
General Counsel
National Community Pharmacists Association
205 Daingerfield Road
Alexandria, VA 22314
(703) 683-8200

KENNETH S. GELLER*
BRITTON B. GUERRINA
Mayer, Brown & Platt
1909 K Street, N.W.
Washington, D.C. 20006
(202) 263-3000

* *Counsel of Record*

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QUESTION PRESENTED

Whether provisions of the Food and Drug Administration Modernization Act of 1997 that permit pharmacist compounding only if the pharmacist "does not advertise or promote the compounding of any particular drug, class of drug, or type of drug" violate the First Amendment.

TABLE OF CONTENTS

Page

QUESTION PRESENTED I

TABLE OF AUTHORITIES iv

INTEREST OF THE AMICUS CURIAE 1

STATEMENT 2

A. Pharmacist compounding has a long, proud history 2

B. Pharmacist compounding and drug manufacturing have long existed side by side 6

C. Millions of patients need pharmacist-compounded drugs 8

D. Pharmacist compounding is legal 10

SUMMARY OF ARGUMENT 15

ARGUMENT 16

BY RESTRICTING ADVERTISING CONCERNING LAWFUL CONDUCT, SECTION 503A VIOLATES THE FIRST AMENDMENT 16

A. Strict scrutiny is the proper standard of review ... 16

B. Section 503A cannot survive strict scrutiny 22

1. The government's asserted goals can be achieved without infringing on pharmacists' fundamental right to free speech 23

2. The speech restrictions are overbroad 24

3. The government's arguments make no sense even on their own terms 27

4. The government cannot regulate conduct indirectly by restricting truthful commercial speech 27

CONCLUSION 29

TABLE OF AUTHORITIES

Page(s)

Cases:

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TABLE OF AUTHORITIES — Continued

Page(s)

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Ga. Code. Ann. § 26-4-4 14

Haw. Rev. Stat. § 461-1 14

Idaho Code § 54-1704 14

225 Ill. Comp. Stat. 85/3 14

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TABLE OF AUTHORITIES — Continued

Page(s)

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Neb. Rev. Stat. § 71-1,142 14

Nev. Rev. Stat. § 639.0124 14

N.H. Rev. Stat. Ann. § 318.1 14

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TABLE OF AUTHORITIES — Continued

Page(s)

63 Pa. Cons. Stat. Ann. § 390-2 14

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BRIEF AMICUS CURIAE OF THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION IN SUPPORT OF RESPONDENTS

INTEREST OF THE AMICUS CURIAE[1]

The National Community Pharmacists Association (NCPA), which was founded in 1898 as the National Association of Retail Druggists (NARD), represents the owners, managers, and employees of 25,000 independent community pharmacies across the United States. The more than 60,000 independent pharmacists nationwide dispense the majority of the Nation's retail prescription drugs. The NCPA is committed to high-quality patient care and to restoring, maintaining, and promoting the health and well-being of the general public.

The NCPA has vigorously opposed the Food and Drug Administration's assertion of jurisdiction over pharmacy compounding. Ten years ago, on its own behalf and as a member of the Joint Commission of Pharmacy Practitioners, the NCPA (then the NARD) met and exchanged several letters with FDA officials regarding the agency's forays into regulating prescription drug compounding. The NCPA also supported passage of proposed legislation to preserve exclusive state jurisdiction over pharmacy compounding (*e.g.*, the bipartisan Pharmacy Compounding Preservation Act of 1995) and participated actively in the congressional debate leading to the passage of the pharmacy compounding provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

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[1] Pursuant to Rule 37.6, *amicus* certifies that no counsel for a party authored this brief in whole or in part, and that no person or entity, other than the *amicus*, its members, or counsel, has made a monetary contribution to this brief's preparation or submission.

Letters from the parties consenting to the filing of this *amicus* brief have been lodged with the Court.

The NCPA undertook those legislative efforts and expresses its views to the Court because compounding is an integral part of pharmacist care – particularly as provided by independent community pharmacists. Through compounding, the prescribing physician and pharmacist can decide a proper course of therapy for each individual patient and ensure that the patient's specific needs are met. The NCPA supports the traditional right of the pharmacist to compound and believes that the new Section 503A of the Food, Drug and Cosmetic Act (FDCA), added by FDAMA and codified at 21 U.S.C. § 353a, threatens the very nature of the practice of pharmacy by unlawfully restricting the right of community retail pharmacists to provide truthful, accurate information to physicians and the public regarding the potential benefits of compounded drugs and compounding services.

STATEMENT

In its brief and in the courts below, the government has questioned the legitimacy of pharmacist compounding. The government concedes that traditional compounding is useful to patient care, but maintains that compounding is sometimes simply a guise to skirt the federal food and drug laws. The lengthy history of pharmacist compounding demonstrates that the government's arguments regarding the legitimacy and legality of compounding are overstated. Traditional pharmacist compounding is integral to the practice of pharmacy. Pharmacist compounding serves a unique and invaluable role in patient care that large-scale drug manufacturing cannot fill, as demonstrated by the fact that traditional pharmacist compounding and drug manufacturing have existed side-by-side for several hundred years.

A. Pharmacist compounding has a long, proud history.

Practiced for literally thousands of years, compounding is the very root of pharmacy. Even in ancient times, the ability to manipulate natural materials to create medications was highly

valued.[2] Indeed, the very definition of "pharmacy" demonstrates the central role of compounding to the profession: "Pharmacy: the art or practice of preparing, preserving, compounding, and dispensing drugs * * * ; a place where medicines are compounded or dispensed."[3] It is thus no surprise that compounding is recognized as "the traditional art" of the pharmaceutical profession.[4]

As the profession of pharmacy developed, compounding remained central to the pharmacist's duties. Compounding has been part of American pharmacy since the colonial period.[5] Just

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[2] David L. Cowen & William H. Helfand, *Pharmacy: An Illustrated History* 20 (1990). In fact, the first recorded medical text, written on clay tablets from Mesopotamia dating from 2100 B.C., provides formulas and directions for compounding. For example, the text instructs the practitioner to "pulverize [the bark of] the apple tree and the 'moon' plant; infuse it with *kushumma* wine; let tree oil and hot [?] cedar oil be spread over it." *Id.* at 19 (emphasis and alterations in original).

[3] *Webster's Third New International Dictionary* 1694 (1986) (emphasis added). See also *The Compact Oxford English Dictionary* 663 (2d ed. 1991) (defining "pharmacy" as "the art or practice of collecting, preparing and dispensing drugs, especially for medicinal purposes; the making or *compounding* of medicines; the occupation of a druggist or pharmaceutical chemist") (emphasis added).

[4] Remarks of David A. Kessler, Commissioner of Food and Drugs, Annual Conference of the American Pharmaceutical Association (Mar. 16, 1992).

[5] For example, the first governor of Connecticut Colony, John Winthrop, Jr., prepared compounds himself and is credited with being one of the first colonists to do pharmaceutical work in North America. *Kremers and Urdang's History of Pharmacy* 153-155 (rev'd by Glenn Sonnedecker, 4th ed. 1976). The first pharmacist to be licensed in North America (in Louisiana in 1770) operated under a regulatory code that required pharmacists to "compound exactly the prescriptions as ordered by the doctor without ever adding anything" and not compound medicines without prescriptions or order drugs on

as in Europe, colonial apothecary shops were lined with shelves full of jars of herbs, minerals, and other drug ingredients, and every pharmacist had on hand the tools to compound the ingredients into medicines, including scales for weighing, crucibles for heating, and mortars and pestles for grinding and mixing.[6] The mortar and pestle are the recognized symbols of the profession of independent pharmacy even today.

The creation and sharing of knowledge regarding the possibilities of pharmaceutical compounding and specific compound drugs have been critical to the development of the profession of pharmacy. Compilations of drug recipes were created even in ancient times. Hippocrates's Corpus Hippocratean mentions drugs, pharmaceutical processes, and dosage forms,[7] and Dioscorides's treatise De materia medica (50-70 A.D.) was used as a reference for centuries.[8] Governments eventually adopted official pharmacopeia, the first of which was published in Nuremberg in 1546.[9] By the nineteenth century, having a well-developed pharmacopeia was a matter of national pride, and countries took care to develop their own lists of official drugs.[10]

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their own accord. Ed Reed, *Wet Graves, Hoodoo Men and Sharp Cats: The History of Pharmacy in Louisiana From the Very Beginning* 13 (1989).

[6] See, *e.g.*, Kremers & Urdang at 156 (listing materials included in inventory of pharmacist's estate in 1725). See also Roscoe Collins Clark, *Threescore Years and Ten: A Narrative of the First Seventy Years of Eli Lilly and Company 1876-1946* 6-7 (1946) (describing the accoutrements of the pharmacy where Eli Lilly worked as an apprentice).

[7] Richard A. Deno, Thomas D. Rowe, & Donald C. Brodie, *The Profession of Pharmacy: An Introductory Textbook* 43 (1959).

[8] Cowen & Helfand at 29.

[9] *Id.* at 68, 91.

[10] See Cowen & Helfand at 137.

A national pharmacopeia for the United States first emerged with the publication of the United States Pharmacopeia in 1820.[11] Early editions distinguished between manufactured drugs and those to be prepared by individual pharmacists. When the 1882 edition de-emphasized the making and compounding of medications in community pharmacies,[12] pharmacists became concerned that the de-emphasis on compounding would lead to the loss of "one of their principal professional functions."[13] In response, the American Pharmaceutical Association developed the National Formulary. First published in 1888, early editions of the National Formulary emphasized the importance of pharmacist compounding to provide flexibility necessary to meet the needs of individual patients.[14] Both the United States Pharmacopeia and the National Formulary were recognized under federal law in 1906 and again in 1938.[15] They retain official legal status today.[16]

Besides pharmacopeia, which compiled drug descriptions and formulae, other materials aided pharmacists in compound-

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[11] Kremers & Urdang at 260-263.

[12] *Id.* at 267.

[13] *Id.* at 275-276.

[14] *Id.* at 275.

[15] *Id.* at 276.

[16] *Id.* at 269. See 21 U.S.C. § 321 (defining "drug" to mean "articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them" and "official compendium" to mean "the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them"). Section 503A also requires pharmacists performing compounding services to comply with the monographs from the United States Pharmacopeia or the National Formulary or the Pharmacopeia's chapter on pharmacy compounding. See 21 U.S.C. § 353a(b)(1)(A)(i)(I).

ing drugs. In 1849, William Procter, Jr., a professor at the Philadelphia College of Pharmacy and the "Father of American Pharmacy,"[17] published Practical Pharmacy: the Arrangements, Apparatus and Manipulations of the Pharmaceutical Shop and Laboratory, based on works of German and British pharmacists.[18] Wilbur L. Scoville published the first edition of The Art of Compounding in 1895. Nine editions of the book were published (the last in 1957).[19] A committee of the American Pharmaceutical Association published The Pharmaceutical Recipe Book, which listed a variety of compounding formulas, in 1929; second and third editions followed in 1936 and 1942.[20] The existence of these materials demonstrates the historic role of compounding in traditional American pharmacy.

B. Pharmacist compounding and drug manufacturing have long existed side by side.

As was the case with many industries and professions, the industrial revolution precipitated many changes in pharmacy, including a gradual de-emphasis on pharmacist compounding. Drug manufacturing began in the United States in the eighteenth century,[21] and took hold in the nineteenth, when pharmacists like Eli Lilly, druggists like Samuel P. Wetherill, and doctors like E.R. Squibb began to mass produce drugs. These and other drug manufacturers, with sophisticated technology and economies of scale, were able to manufacture and distribute many drugs to the local pharmacy. They could also invest

[17] See American Institute of the History of Pharmacy homepage, <http://www.pharmacy.wisc.edu/aihp/> (visited Jan. 9, 2001).

[18] Cowen & Helfand at 143.

[19] Kremers & Urdang at 285.

[20] *Id.* at 281.

[21] Large-scale manufacturing of pharmaceutical chemicals probably first occurred in the United States in 1786 by a firm of wholesale and retail druggists in Philadelphia. See Kremers & Urdang at 326.

money in research to develop new drug combinations and delivery mechanisms (like coated tablets).[22]

Large-scale manufacturing of drugs and drug ingredients was not entirely an advent of the industrial revolution, however. Pharmacopeia often included both instructions for compounding drugs and descriptions of medications manufactured in bulk. For example, one of the earliest American pharmacopeia – the "Lititz pharmacopeia" (1778), a military formulary used in the Revolutionary War – described both medicines to be created in bulk and distributed for use as well as those to be compounded locally in hospital dispensatories.[23] Similarly, the early editions of the United States Pharmacopeia distinguished between manufactured drugs and those to be compounded by local pharmacists.[24]

For many years drug manufacturers and compounding pharmacists worked hand-in-hand. Despite the rapid growth of pharmaceutical manufacturing, until relatively recently most prescriptions continued to be filled through compounding.[25] For example, in the 1920s up to 80 percent of prescriptions required the pharmacist to have a good knowledge of compounding.[26] Thus, even as pharmaceutical manufacturing developed, a

[22] See generally *id.* at 314-315, 328-332; Cowen & Helfand at 175-180.

[23] Kremers & Urdang at 169-170.

[24] Indeed, the preface to the first edition (1820) reflects the emergence of large-scale drug manufacturing: "Those compound substances which are prepared in the large way at manufactories, and which are to be kept by the apothecary, though not necessarily prepared by him, are inserted on the materia medica list. Those which are to be made by the apothecary alone, are placed among the preparations and compositions." Kremers & Urdang at 263 (quoting United States Pharmacopeia at 22 (1820)).

[25] Kremers & Urdang at 315.

[26] Cowen & Helfand at 186.

major component of the drug manufacturing business consisted of providing pharmacies with drug ingredients and formulae for use by pharmacists in compounding.[27]

Over time, however, the proportion of prescriptions requiring compounding or other sorts of professional manipulation by the pharmacist declined and compounding gradually began to play a less central role in American pharmacy. In the early 1930s, 75 percent of prescriptions required a pharmacist trained in compounding. In 1950, 26 percent of prescriptions required compounding, but by 1962 the percentage was less than 5. The number of prescriptions filled through compounding has hovered around 5 percent ever since.[28]

C. Millions of patients need pharmacist-compounded drugs.

Although it is now the exception rather than the norm, pharmacist compounding continues to play a crucial role in public health. Mass-produced, manufactured drugs meet the needs of most patients, but they do not meet the needs of all of them. As pharmacists and physicians have become reacquainted with how compounding can be used to tailor medications to

[27] See, *e.g.*, N.A.R.D. J. 1941 (Dec. 1, 1952) (advertisement by Mallinckrodt Chemical Works for prescription chemicals for use in compounding, including testimonial by experienced compounding pharmacist); N.A.R.D. J. 1685 (Oct. 16, 1950) (advertisement by Mallinckrodt Chemical Works for "compoundable chemicals for precision compounding"); N.A.R.D. J. 946D (June 21, 1948) (advertisement for "Mercurochrome" brand of merbromin, dibromoxymercurifluoresceine-sodium in four forms for pharmacists to use in preparing various solutions); N.A.R.D. J. 1729 (Sept. 15, 1947) (advertisement by Merck & Co. for prescription chemicals).

[28] Kremers & Urdang at 315; *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 752, 766 (1976) (estimating that in the mid-1970s 5 percent of prescriptions were filled through compounding).

meet the needs of individual patients, compounding has undergone a renaissance. The precise number of prescriptions currently filled through compounding is not known, but estimates vary between 1 and 10 percent of all prescriptions filled. The numbers may appear small as a relative matter, but they indicate that millions of patients require the services of a compounding pharmacist in order to have their medication needs satisfactorily met.[29]

The need for compounding persists for many reasons. Some patients are not able to use a medication in its manufactured form: for example, the dye or lactose coating may trigger an allergic reaction, a pill may be difficult or uncomfortable to swallow, or the dose may be too strong. In these instances, the pharmacist can customize the medication especially for the patient by making it without the dye or lactose,[30] putting it in a different delivery form (such as a transdermal stick or suppository),[31] or lowering the dosage.[32] Sometimes a patient may need a drug that is no longer produced because the manufacturer has gone out of business or the drug is not economical to mass produce; in that case, the independent pharmacist can re-create

[29] In 2000, approximately 3 billion prescriptions were dispensed. See Larry Levitt, *Prescription Drug Trends* chart 3 (Henry J. Kaiser Family Foundation Nov. 2001). Assuming compounding constitutes 1 percent of all prescriptions filled, that means approximately 30 million prescriptions were compounded. Approximately 83 percent of independent pharmacies report that they provide compounding services. See *NCPA-Pharmacia 2001 Digest* 14, 18, 23 (2001).

[30] See, *e.g.*, Chris O'Malley, *Small pharmacies customizing again*, Indianapolis News (Aug. 27, 1996).

[31] See, *e.g.*, Winda Benedetti, *Masters of the mortar and pestle*, Spokesman Rev. (July 4, 1999).

[32] See, *e.g.*, Melinda Voss, *Made-to-order medications*, Des Moines Register (Oct. 20, 1997).

the drug through compounding.[33] Sometimes, as with children, the best way to ensure that the patient complies with the prescription is to mask the medication in a candy-like flavor and form.[34] Compounding can even be useful to medicate finicky pets.[35] Thus, through compounding, pharmacists can ensure that all patients – regardless of their individual needs and circumstances – are able to receive the drug therapies they require.[36]

D. Pharmacist compounding is legal.

The government's argument turns in part on its assertion that all compounded drugs are subject to the new drug approval requirements of the FDCA. In the government's view, the compounding pharmacist "creates a 'new drug' because the compounded product is not 'generally recognized, among experts * * *, as safe and effective.'"[37] The government thus contends that all compounding – even the traditional compounding performed by pharmacists – is subject to the FDCA.[38] However, this understanding of the FDCA's reach is a recent creation.

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[33] See, *e.g.*, Marmian L. Grimes, *Pharmacist receives national recognition for compounding*, Fairbanks Daily News-Miner (Apr. 3, 1999).

[34] See, *e.g.*, *Local Pharmacy Makes Kids' Medicine Taste Sweet*, Mt. Prospect J. (Apr. 28, 1999).

[35] See, *e.g.*, Amy Calder, *Oakland pharmacy not generic*, Morning Sentinel (May 16, 1997).

[36] See generally Mitchell J. Ghen & John R. Rains, *The Ghen and Rains Physicians' Guide to Pharmaceutical Compounding* 27-29 (2000).

[37] U.S. Br. 4 (quoting 21 U.S.C. § 321(p)(1)).

[38] *Id.* at 4-5, 18-19, 25. Taking the government at its word, if a pharmacist compounds a single dose of a drug in response to a physician's prescription and does not seek FDA approval, that pharmacist is violating the FDCA.

The new drug approval requirements of the FDCA, codified at 21 U.S.C. § 355, were added to the food and drug reform legislation pending in 1937-1938 in response to the deaths of more than 100 people who took a noncompounded drug called "Elixir Sulfanilmide."[39] The history of the new drug provisions indicates that the Sulfanilmide scandal prompted congressional concern regarding the safety of manufactured drugs – particularly those not recognized by the National Formulary or the United States Pharmacopeia. Drugs compounded by pharmacists were not a focus of the congressional or public debate,[40] and nothing in the FDCA legislative history even suggests that pharmacist compounding was covered by the statute.

This is not at all surprising because, at the time the FDCA was enacted, compounding by independent pharmacists was the standard practice by which prescriptions were filled – and continued to be for the next 10 to 20 years.[41] If the FDCA had

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[39] Although new food and drug legislation had been pending for years when the "Elixir Sulfinalmide" scandal arose, the pending legislation did not provide for safety testing of new drugs. In response to the scandal, language was added to the pending legislation that forbade the introduction into interstate commerce of "any drug * * * not generally recognized as safe for use." David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 J. L. & Contemp. Probs. 2, 20 (1939) (quoting S. 3073, 75th Cong. (2d Sess. 1938)). See also Vincent A. Kleinfeld, *Legislative History of the Federal Food, Drug, and Cosmetic Act*, 50 Food & Drug L. J. 65, 92-93 (1995); Kremers & Urdang at 221.

[40] For example, two Senate reports do not even mention compounding. See S. Rep. No. 75-91 (1937); S. Rep. No. 75-152 (1937). See also Cavers, 6 J. L. & Contemp. Probs. at 32-34, 40 (discussing development and scope of FDCA drug provisions).

[41] In the 1930s when the FDCA was enacted, approximately 75 percent of all prescriptions were filled through pharmacist compounding. See page 8, *supra*. As children of the 1930s

radically overhauled the practice of pharmacy by outlawing compounding, one would expect that those provisions of the FDCA would have received significant attention both in the legislative history and in public discourse. But no evidence of such attention exists. Indeed, for 50 years, no one – not even the FDA – interpreted the FDCA's statutory language to reach traditional pharmacist compounding. Like the dog that did not bark, the silence on this matter indicates that there was, in fact, no such intent.[42]

In short, although since 1992 the FDA has argued that the FDCA provides it with authority to regulate all compounding,[43] the historical understanding of the statute demonstrates that this is not so.[44] Just as the agency attempted unsuccessfully in

undoubtedly remember, filling a prescription sometimes meant observing the local pharmacist make the medication called for in the prescription.

[42] See, *e.g.*, *Chisom* v. *Roemer*, 501 U.S. 380, 396 & n.23 (1991) (likening Congressional silence to "the dog that did not bark") (citing A. Doyle, "Silver Blaze," in *The Complete Sherlock Holmes* 335 (1927)); *Harrison* v. *PPG Indus., Inc.*, 446 U.S. 578, 602 (1980) (Rehnquist, J., dissenting) ("In a case where the construction of legislative language such as this makes so sweeping and so relatively unorthodox a change as that made here, I think judges as well as detectives may take into consideration the fact that a watchdog did not bark in the night.").

[43] See FDA Compliance Guide (CPG) 7132.16 (Mar. 16, 1992).

[44] The government (at 6) points to two counter examples. However, these cases clearly involved large-scale drug manufacturing and thus do not address whether traditional pharmacist compounding falls within the parameters of the FDCA. See *United States* v. *Sene X Eleemosynary Corp.*, 479 F. Supp. 970, 978 (S.D. Fla. 1979) ("The question of whether the customary or usual practice of pharmacy is exempt from the [FDCA's] new drug provisions need not be resolved in this case, for the means by which the defendants compound, promote, and ultimately distribute GH-3 constitute something wholly

FDA v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), the FDA is again using ambiguity in statutory language to expand retroactively a statute into areas where it was never intended to go.[45]

Moreover, the government's reading of the statute borders on the absurd, because it would make little sense to construe the FDCA to require new drug approval every time an individual patient needs a customized drug. Under such a reading, many patients would never receive necessary medication, because it would either never be created (given the cost of the approval process) or be created too late (given the length of the approval process).[46] It is hard to believe that Congress meant the new drug approval process to deprive people with unique needs of necessary (and potentially life saving) pharmacist-compounded drugs.

That traditional pharmacist compounding is legal is further supported by its status in the 50 states. It is the states, of course, not the FDA, that license and regulate pharmacists and individual pharmacies. All of the states treat compounding as

apart from the normal practice of pharmacy."); *Cedars N. Towers Pharmacy, Inc.* v. *United States*, [1978-1979 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,200, at ¶ 38,828 (S.D. Fla. Aug. 28, 1978) ("Bulk compounding of drugs at wholesale prices with nationwide distribution is not the type of activity intended to be exempt from registration [as a drug manufacturer].").

[45] See *Brown & Williamson*, 529 U.S. at 146-147 ("[T]here is no evidence in the text of the FDCA or its legislative history that Congress in 1938 even considered the applicability of the Act to tobacco products. Given the economic and political significance of the tobacco industry at the time, it is extremely unlikely that Congress could have intended to place tobacco within the ambit of the FDCA absent any discussion of the matter.") (citation omitted).

[46] See U.S. Br. 26-27.

fundamental to the practice of pharmacy,[47] and compounding is an integral part of every state's definition of pharmacy.[48] In addition, the North American Pharmacist Licensure Examination (NAPLEX®) requires that candidates demonstrate some

[47] Ala. Code § 34-23-1; Alaska Stat. § 08.80.480; Ariz. Rev. Stat. § 32-1901; Ark. Code Ann. § 17-92-101; Cal. Bus. & Prof. Code § 4037; Colo. Rev. Stat. § 12-22-102; Conn. Gen. Stat. § 20-571; Del. Code. Ann. tit. 24, § 2502; Fla. Stat. ch. 465.003; Ga. Code. Ann. § 26-4-4; Haw. Rev. Stat. § 461-1; Idaho Code § 54-1704; 225 Ill. Comp. Stat. 85/3; Ind. Code § 25-26-13-2; Iowa Code § 155A.3; Kan. Stat. Ann. § 65-1626a; Ky. Rev. Stat. Ann. § 315.010; La. Rev. Stat. Ann. § 1164; Me. Rev. Stat. Ann. § 13702; Md. Code Ann. 12-101; Mass. Gen. Laws ch. 94, § 187; ch. 94C, § 1; Mich. Comp. Laws § 33.17707; Minn. Stat. § 151.01; Miss. Code Ann. § 73-21-73; Mo. Rev. Stat. § 338.010; Mont. Code Ann. § 37-7-101; Neb. Rev. Stat. § 71-1,142; Nev. Rev. Stat. § 639.0124; N.H. Rev. Stat. Ann. § 318.1; N.J. Stat. Ann. § 13:39-1.2; N.M. Stat. Ann. § 61-11-2; N.Y. Educ. Law § 6801; N.C. Gen. Stat. § 90-85.3; N.D. Cent. Code. § 43-15-01; Ohio Rev. Code Ann. § 4729.01; Okla Stat. tit. 59, § 353.1; Or. Rev. Stat. § 689.015; 63 Pa. Cons. Stat. Ann. § 390-2; R.I. Gen. Laws § 5-19-19; S.C. Code Ann. § 40-43-30; S.D. Codified Laws § 36-11-2.2; Tenn. Code Ann. § 63-10-404; Tex. Occ. Code Ann. § 551.003; Utah Code Ann. § 58-17a-102; Vt. Stat. Ann. tit. 26, § 2022; Va Code Ann. § 54.1-3300; Wash. Rev. Code § 18.64.011; W. Va. Code § 30-5-1b; Wisc. Stat. § 450.01; Wyo. Stat. Ann. § 33-24-124. See also Sen. Rep. No. 105-43, at 64 (1997).

[48] See, *e.g.*, Ind. Code § 25-26-13-2. ("'Pharmacy' means any facility, department, or other place where prescriptions are filled or compounded[.]"); Iowa Code § 155A.3(24) ("'Pharmacy' means a location where prescription drugs are compounded, dispensed, or sold by a pharmacist[.]"); Ky. Rev. Stat. Ann. § 315.010 ("'Pharmacy' means every place where * * * (b) Prescription drug orders are compounded under the direction of a pharmacist[.]"); Miss. Code Ann. § 73-21-73 ("'Practice of pharmacy' shall mean a health care service that includes, but is not limited to, the compounding, dispensing, and labeling of drugs or devices[.]").

competency in compounding.[49] Compounding also remains part of the standard pharmacy school curriculum.[50] In sum, when independent pharmacists offer and sell compounding services and particular compounded drugs, they are engaging in lawful actions. The FDAMA thus restricts community pharmacists from promoting, advertising, and soliciting completely lawful products and services.[51]

SUMMARY OF ARGUMENT

For many years the FDCA new drug approval requirements (among others) were not applied to traditional pharmacist compounding, and little to no evidence suggests that anyone – pharmacists, physicians, Congress, or the FDA – even contemplated that the FDCA allowed the federal government to prohibit or regulate traditional pharmacist compounding. That

[49] See NAPLEX Competency Statements 2.1.0 ("Perform calculations required to compound, dispense, and administer medication."), 2.3.0 ("Prepare and compound extemporaneous preparations and sterile products.").

[50] The American Council of Pharmaceutical Education (ACPE) accreditation standards include compounding among the professional competencies and outcome expectations for pharmacy students. See *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* (Adopted June 14, 1997) Standard 10.a ("* * * accurately and safely compound drugs in appropriate dosage forms * * *"). See also American Association of Colleges of Pharmacy Center for the Advancement of Pharmaceutical Education *Educational Outcomes* (Nov. 15, 1998) § I(E)(2) ("Accurately compound individual or bulk medications.").

[51] Even if the "new drug" provisions of the FDCA could be construed to cover the drugs compounded by pharmacists, that alone would not make the practice unlawful. Instead, that would simply mean that the FDA could bring an enforcement action against those pharmacies that shipped inordinate amounts of compounded drugs across state lines.

changed when the FDA began a series of enforcement measures against pharmacies engaged in compounding. In response, Congress attempted to settle any ambiguity regarding the FDCA's scope by expressly exempting pharmacist compounding from various FDCA requirements.[52] However, as a condition of the exemption, Congress required all compounding pharmacists – including those engaged exclusively in traditional compounding – to refrain from advertising or promoting particular compounded drugs or from soliciting business for their compounding services.[53] In so doing, Congress violated the First Amendment.

The district court and the Ninth Circuit struck down Section 503A's speech restrictions as unconstitutional under the balancing test of *Central Hudson Gas & Electric Corp.* v. *Public Service Commission of New York*, 447 U.S. 557 (1980). The district and circuit courts correctly determined that Section 503A is unconstitutional under *Central Hudson*; however, the NCPA urges the Court to review Section 503A under a more exacting standard of review. Strict scrutiny is appropriate in this instance because Section 503A prohibits the dissemination of truthful and accurate information, is not related to the preservation of a fair bargaining process, and restricts speech based on its content and viewpoint. Applying strict scrutiny, Section 503A does not pass constitutional muster.

ARGUMENT

BY RESTRICTING ADVERTISING CONCERNING LAWFUL CONDUCT, SECTION 503A VIOLATES THE FIRST AMENDMENT

A. Strict scrutiny is the proper standard of review.

The government's ability to regulate commercial speech is

[52] See 21 U.S.C. § 353a.

[53] See *id.* § 353a(a), (c).

an extension of its ability to regulate commercial transactions.[54] Regulation of commercial transactions is permitted to ensure that both parties at the bargaining table – and consumers in particular – are treated fairly and that one party does not take advantage of the other. In order to "preserve a fair bargaining process," the government may regulate the information presented to consumers by proscribing false and misleading advertising and mandating the disclosure of additional information in the form of warnings and disclaimers.[55] Similarly, the government may proscribe particular methods or devices for advertising goods and services to prevent consumers from being harassed or unduly influenced, or to prevent their bargaining partners from overreaching.[56] These interests are reflected in the balancing test adopted in *Central Hudson*.[57]

However, since the adoption of the *Central Hudson* balancing test, seven Justices have stated that restrictions of truthful commercial speech should be reviewed under strict rather than intermediate scrutiny. In *Central Hudson* itself, Justice Blackmun noted that the balancing test adopted by the majority "does not provide adequate protection for truthful, nonmisleading, noncoercive commercial speech concerning lawful activities."[58] Justice Brennan expressed similar dissatis

[54] See *Central Hudson*, 447 U.S. at 561; *Friedman* v. *Rogers*, 440 U.S. 1, 10 n.9 (1979); *Ohralik* v. *Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978).

[55] See *Virginia State Bd. of Pharmacy*, 425 U.S. at 772 n.24.

[56] See *Florida Bar* v. *Went for It, Inc.*, 515 U.S. 618, 630 (1995); *Ohralik*, 436 U.S. at 462.

[57] 447 U.S. at 566.

[58] *Id.* at 573 (Blackmun, J., joined by Brennan, J., concurring in the judgment). See also *City of Cincinnati* v. *Discovery Network, Inc.*, 507 U.S. 410, 431, 436 (1993) (Blackmun, J., concurring) (suggesting that "truthful, noncoercive commercial speech concerning lawful activities is entitled to full First Amendment

faction with the *Central Hudson* test as it applies to prohibitions and regulations of truthful, nonmisleading speech.[59]

In *44 Liquormart, Inc.* v. *Rhode Island*, 517 U.S. 484 (1996), a majority of the Court's current Members concluded that intermediate scrutiny under *Central Hudson* is not appropriate for all commercial speech restrictions. Specifically, Justices Stevens, Kennedy, and Ginsburg rejected the notion that "all commercial speech regulations are subject to a similar form of constitutional review" and concluded instead that "when a State entirely prohibits the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining process, there is far less reason to depart from the rigorous review the First Amendment generally demands."[60] Justice Thomas observed that there is no "historical basis for asserting that 'commercial' speech is of 'lower value' than 'noncommercial speech'" and explained that intermediate scrutiny was inappropriate "at least when, as here, the asserted interest is one to be achieved through keeping would-be recipients of the speech in the dark."[61] Justice Scalia also expressed "discomfort with the *Central Hudson* test" and argued that regulations of commercial speech should be governed according to "the long accepted practices of the American people."[62] *44 Liquormart* thus raised the question of whether intermediate scrutiny applies to *all* regulation of

protection").

[59] See *Posadas de Puerto Rico Assocs.* v. *Tourism Co.*, 478 U.S. 328, 350 (1986) (Brennan, J., joined by Marshall & Blackmun, JJ., dissenting) ("I see no reason why commercial speech should be afforded less protection than other types of speech where, as here, the government seeks to suppress commercial speech in order to deprive consumers of accurate information concerning lawful activity.").

[60] 517 U.S. at 501 (plurality).

[61] *Id.* at 522 (Thomas, J., concurring).

[62] *Id.* at 517 (Scalia, J., concurring in the judgment).

commercial speech or whether intermediate scrutiny applies only when the regulation relates to the governmental interest in preserving a fair bargaining process (by preventing false, misleading, or overbearing speech or speech that relates to unlawful activities).

In two recent cases, the Court expressly noted the uncertain scope of *Central Hudson* and the chorus of calls for its repudiation.[63] However, because in each case the challenged speech restrictions were unconstitutional even under *Central Hudson*'s intermediate scrutiny test, the question whether certain circumstances might justify applying strict scrutiny to (at least) some commercial speech was reserved for another day.[64] This case presents an opportunity to revisit and settle this recurring debate.

Section 503A should be assessed under strict scrutiny for two reasons. First, strict scrutiny applies because Section 503A does not "protect consumers from misleading, deceptive, or aggressive sales practices" or "requir[e] the disclosure of beneficial consumer information," but "prohibits the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining

[63] See *Lorillard Tobacco Co.* v. *Reilly*, 121 S. Ct. 2404, 2421 (2001) ("Petitioners urge us to reject the *Central Hudson* analysis and apply strict scrutiny. * * * Admittedly, several Members of the Court have expressed doubts about the *Central Hudson* analysis and whether it should apply in particular cases."); *Greater New Orleans Broad. Ass'n, Inc.* v. *United States*, 527 U.S. 173, 184 (1999) ("[C]ertain judges, scholars, and *amici curiae* have advocated repudiation of the *Central Hudson* standard and implementation of a more straightforward and stringent test for assessing the validity of governmental restrictions on commercial speech.").

[64] See *Lorillard*, 121 S. Ct. at 2421, 2428; *Greater New Orleans*, 527 U.S. at 184.

process."[65] Because the government has not attempted to justify Section 503A by pointing to any overreaching, undue influence, or fraud that deprives consumers of a "fair bargaining process," under the plurality's test in *44 Liquormart*, strict scrutiny applies.

The Court's decision in *R.A.V.* v. *City of St. Paul*, 505 U.S. 377 (1992), supports the application of strict scrutiny for the same reason. In *R.A.V.*, the Court held that strict scrutiny applies to content-based restrictions that are not related to the "distinctively proscribable content" of the (unprotected) category of speech at issue. Commercial speech is proscribable to the extent it is false, misleading or relates to an illegal activity. Because Section 503A's restrictions are not intended to prevent the dissemination of false or misleading information or otherwise preserve a fair bargaining process (the proscribable content of commercial speech), under *R.A.V.*,"they are presumptively invalid."[66]

Second, strict scrutiny is appropriate because Section 503A's restrictions are content- and viewpoint-based. Under First Amendment principles the Court has long emphasized,

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[65] *44 Liquormart*, 517 U.S. at 501 (plurality opinion). See also *Carey* v. *Population Servs., Int'l*, 431 U.S. 678, 700 (1977) (noting that a statute that "seeks to suppress completely any information about the price and availability of [a product]" is unconstitutional).

[66] See 505 U.S. at 382-384. As the Court explained, "a State may choose to regulate price advertising in one industry but not in others, because the risk of fraud (one of the characteristics of commercial speech that justifies depriving it of full First Amendment protection) is in its view greater there. But a State may not prohibit only that commercial advertising that depicts men in a demeaning fashion." *Id.* at 388-389 (citations omitted). Similarly, in *44 Liquormart*, four Justices found it "perfectly clear" that a State "could not ban all obscene liquor ads except those that advocated temperance." 517 U.S. at 513 (plurality).

content-based speech restrictions are highly suspect,[67] and viewpoint-based restrictions are even more so.[68] These basic First Amendment principles have been expressed in the commercial speech context,[69] and the Court has invalidated commercial speech restrictions that were impermissibly content based.[70]

There can be no dispute that Section 503A is content-based. It prohibits speech only if it relates to the benefits of particular pharmacist-compounded drugs. Section 503A is also viewpoint-based. It prohibits only that speech that "promotes" com-

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[67] See, *e.g.*, *R.A.V.*, 505 U.S. at 382 ("Content-based regulations are presumptively invalid."); *Carey* v. *Brown*, 447 U.S. 455, 462-463 (1980) ("Any restriction on expressive activity because of its content would completely undercut the profound national commitment to the principle that debate on public issues should be uninhibited, robust, and wide-open.") (citation and internal quotation marks omitted).

[68] See, *e.g.*, *Rosenberger* v. *Rector & Visitors of Univ.*, 515 U.S. 819, 829 (1995) ("When the government targets not subject matter but particular views taken by speakers on a subject, the violation of the First Amendment is all the more blatant."); *Texas* v. *Johnson*, 491 U.S. 397, 414 (1989) ("If there is a bedrock principle underlying the First Amendment, it is that the government may not prohibit the expression of an idea simply because society finds the idea itself offensive or disagreeable.").

[69] See *44 Liquormart*, 517 U.S. at 499 ("[T]he State retains less regulatory authority when its commercial speech restrictions strike at 'the substance of the information communicated' rather than the 'commercial aspect of [it] – with offerors communicating offers to offerees.'") (quoting *Linmark Assocs., Inc.* v. *Willingboro Township*, 431 U.S. 85, 96 (1977)); *Carey*, 431 U.S. at 701 n.28 (content-based commercial speech regulations "directed not at any commercial aspect of the prohibited advertising, but at the ideas conveyed," violates "the core of First Amendment values").

[70] See, *e.g.*, *Discovery Network*, 507 U.S. at 428-430; *Linmark*, 431 U.S. at 96.

pounded drugs and thus disfavors a particular viewpoint. (The restriction means that large drug manufacturers are free to criticize particular pharmacist-compounded drugs, but pharmacists are prevented from presenting their benefits.) Thus, under settled First Amendment principles, Section 503A should be assessed under strict scrutiny because it suppresses a large amount of truthful commercial speech and threatens to "effectively drive certain ideas or viewpoints from the marketplace."[71]

B. Section 503A cannot survive strict scrutiny.

As explained above, Section 503A prohibits entirely truthful speech informing consumers about the availability of lawful and beneficial pharmacist-compounded drugs. It does not protect consumers from false or misleading commercial speech or speech that is overbearing. The government's interest is not to protect consumers or prevent them from being misled.[72]

Rather, the government claims (at 20-23) that the purpose of Section 503A's speech restriction is to maintain the integrity

[71] *R.A.V.*, 505 U.S. at 387 (citation and internal quotation marks omitted). See also *44 Liquormart*, 517 U.S. at 501 ("Our commercial speech cases have recognized the dangers that attend governmental attempts to single out certain messages for suppression.").

[72] At one point in this litigation, the government argued that Section 503A's speech restrictions are necessary because consumers are ill-equipped to understand and evaluate materials advertising and promoting pharmacist compounding services and pharmacist-compounded drugs and, specifically, might assume that pharmacist-compounded drugs have gone through the FDA approval process. See *Western States Medical Ctr.* v. *Shalala*, 69 F. Supp. 2d 1288, 1299 (D. Nev. 1999), *aff'd in part, rev'd in part*, 238 F.3d 1090 (9th Cir. 2001). The district court rejected this argument because the government presented no evidence to demonstrate that consumers are likely to misunderstand or misinterpret advertising regarding pharmacist-compounded drugs, nor did it show that less restrictive requirements (such as disclaimers) were insufficient to prevent miscommunication. See *id.* at 1299-1300.

of the FDA new drug approval process. According to the government (at 28-29), compounding provides a loophole by which drug manufacturers can directly market their wares to consumers without complying with FDCA requirements (including new drug approval and labeling). The government maintains, in essence, that it must restrict pharmacist speech in order to make that loophole as small and unattractive as possible.[73]

The government contends that restrictions on independent pharmacist speech are critical to its plan because the restrictions will decrease consumer demand for compounded drugs, which, in turn, will make it less likely that manufacturers will take advantage of the compounding loophole. This argument is based on two assumptions. First, because pharmacists do not need FDA approval in order to sell their compounded drugs, they have an unfair competitive advantage over drug manufacturers. In order to level the playing field and maintain drug manufacturers' incentive to comply with the FDA approval requirements, a market for particular compounded drugs cannot be allowed to develop. Second, if consumers do not know about particular compounded drugs, they will be less likely to ask for them. Manufacturers, in turn, will be less tempted to circumvent the FDCA through compounding if they cannot advertise their "compounded" drugs to stimulate consumer demand.

1. The government's asserted goals can be achieved without infringing on pharmacists' fundamental right to free speech.

The government cannot demonstrate that speech restrictions are necessary to achieve its stated goal of preserving the

[73] The government's argument, however, is apparently more hypothetical than real, since it has not presented evidence demonstrating that drug manufacturers have used pharmacies as "fronts" to manufacture drugs or that a large number of community pharmacies regularly manufacture medications in bulk.

integrity of the FDA approval process. The asserted governmental interest here is to prevent covert drug manufacturing. The government should address that problem directly. The current food and drug laws provide ample room for the FDA to stop large-scale manufacturing and marketing of unapproved drugs, as the government's prior enforcement actions demonstrate.[74] In addition, the other conditions of Section 503A, *e.g.*, limitations on out-of-state shipments, are an attempt to address this goal directly.

The government argues that the speech restrictions are necessary to achieve its goal because advertising and promotion are proxies for manufacturing. But the proxy is far from perfect. Promotion and advertising are not related exclusively to manufactured goods: even companies that provide completely customized products advertise and promote what they can do, including providing specific examples of particular products. The fact that a company manufactures a product may be a good predictor of whether or not it will promote and advertise that product, but the fact that a company advertises and promotes products and services is not a good indicator of whether those products and services are manufactured on a large scale or are customized creations.

2. The speech restrictions are overbroad.

The FDAMA speech restrictions, as the government explains, are intended to prevent unregulated manufacture of drugs under the guise of compounding. But the speech regulations prohibit advertising of *all* compounded drugs – even those compounded by community pharmacists who are clearly uninvolved in covert drug manufacturing. Section 503A's plain language prohibits pharmacists engaged in traditional compounding from advertising any particular compounded drugs or classes of drugs, even though the government does not dispute

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[74] See, *e.g.*, *Sene X Eleemosynary*, *supra*; *Cedars N. Towers Pharmacy*, *supra*.

that by compounding such drugs the pharmacist is performing an invaluable public health service.

In the government's view, prohibiting advertising of pharmacist-compounded drugs is permissible because advertising is not "necessary" to traditional compounding as performed by community pharmacists.[75] It may be true that advertising and promotion are not critical to the practice, but that does not mean that community pharmacists who offer compounding services have no interest in promoting their services and advertising particular compounded drugs. To the contrary, like other professionals, they have a strong interest in ensuring that the public is aware of the services and products they can provide.[76]

The government asserts (at 40, 43) that generic advertising regarding the availability of compounding services suffices to meet this need. But that is plainly not so. Advertising concerning the availability of a *particular* pharmacist-compounded drug is far more effective in helping consumers and physicians understand how compounding can help them than information about compounding in general. Many people may not understand what "compounding" services are or how they can assist them. Accordingly, an advertisement explaining only that the pharmacist can "compound" drugs will not inform the parent of a child who will not take his medicine that the pharmacist can make the medicine taste like the child's favorite candy. On the other hand, an advertisement for strawberry or peppermint flavored ampicillin would get the message across.

The FDAMA speech restrictions are also overbroad because they do not circumscribe advertising, promotion, and solicitation to the general public alone. Rather, Section 503A prohibits

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[75] See U.S. Br. 34.

[76] See, *e.g.*, *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 354, 383 (1977) (attorneys); *Virginia State Bd. of Pharmacy*, 425 U.S. at 762 (pharmacists).

all advertising and promotion of compounding services and compounded drugs, including that directed to physicians – a highly educated audience that is capable of understanding and evaluating such information and using it judiciously. When an independent pharmacist and physician discuss medication possibilities, the conversation is between equals. Each may have a particular expertise, but they both are capable of deciphering and understanding sophisticated and complicated medical information. Any concern that physicians will be misled by or unable to understand advertising regarding the compounding of specific drugs is entirely unfounded.

Limiting information to doctors also cannot be justified on the grounds of overreaching or undue influence. The provision of accurate factual information through promotion and advertising does not sway or influence the doctor's choice of therapy. Such is allegedly the case with some marketing tools – *e.g.*, free tickets, meals, or other perks – used by drug companies to sell manufactured drugs to physicians,[77] but there is no hint of that here. Without good reason, Section 503A simply prevents physicians (and their patients) from receiving potentially useful – and even necessary – information regarding alternatives to mass-produced, one-size-fits-all drug products.

[77] This practice has garnered substantial criticism within and without the medical profession, because some believe doctors may be unduly influenced in deciding what drugs to prescribe to their patients. See, *e.g.*, Joseph P. Shapiro & Stacey Schultz, *Prescriptions: How Your Doctor Makes the Choice*, U.S. News & World Rept. 58 (Feb. 19, 2001); Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift*, 283 J. Am. Med. Assoc. 373-380 (2000); Warren E. Leary, *Doctors Given Millions by Drug Companies*, N.Y. Times B13 (Dec. 12, 1990). Notably, however, the federal government does not prohibit this type of advertising or solicitation.

3. The government's arguments make no sense even on their own terms.

The government's arguments are also wholly unpersuasive even on their own terms. To begin with, there is no evidence that the demand for pharmacist-compounded drugs and pharmacists' compounding services is artificially high – that is, that advertising has led more people to demand pharmacist-compounded drugs than actually require them.

Moreover, the government presumes that compounding pharmacists compete with drug manufacturers in a meaningful sense. This concern is exaggerated, to say the least. Although compounding is important to public health and assists millions of patients, the fact remains that, at the very most, no more than 10 percent of prescriptions nationwide are filled through pharmacist compounding.

Finally, it is unlikely that most drug manufacturers would forgo FDA approval, even if given the chance. As the international "gold standard" for prescription medications, FDA approval opens up access not only to the U.S. market but to markets worldwide.[78] Pharmaceutical companies are unlikely to dispense with the FDA imprimatur, if doing so would mean losing access to these markets as well as valuable reputational and marketing benefits. There is thus no demonstrated need to close the compounding "loophole" in the manner set forth by the FDAMA.

4. The government cannot regulate conduct indirectly by restricting truthful commercial speech.

Government prohibitions on commercial speech contravene the First Amendment when, rather than protect consumers from false or misleading information, they are designed to shield

[78] See, *e.g.*, *U.S. Drugs Speed to Russian Markets*, FDA Consumer 4 (May 1994); Dixie Farley, *FDA's Global Reach to Protect Public Health*, FDA Consumer 6 (Nov. 1986).

consumers from the truth or regulate their or others' conduct indirectly: a governmental interest in keeping consumers "ignorant in order to manipulate their choices in the marketplace" is "per se illegitimate."[79]

In this instance, Congress is restricting pharmacists' speech in an attempt to regulate their and drug manufacturers' conduct indirectly. Paternalism is (apparently) not the motivating factor behind the speech restrictions, but Section 503A nonetheless aims to regulate an industry through consumer ignorance: if consumers are ignorant of pharmacist-compounded drugs, they will likely request only manufactured products, and drug manufacturers will continue to comply with the various FDCA requirements. Given that the government cannot limit information and restrict speech in order to prevent the public from receiving information that is potentially dangerous or harmful, the government certainly cannot restrict speech simply because it has decided it wants to manipulate consumer demand to prop up its regulatory scheme. Rather than impinge on the constitutional rights of pharmacists and consumers, the government should achieve its goals directly by regulating the conduct of those who violate the FDCA.[80]

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[79] *44 Liquormart*, 517 U.S. at 518 (Thomas, J., concurring in part); see also *id.* at 517 (Scalia, J., concurring in part) (expressing "aversion towards paternalistic governmental policies that prevent men and women from hearing facts that might not be good for them").

[80] See *Central Hudson*, 447 U.S. at 564 (noting "the Court has declined to uphold regulations that only indirectly advance the state interest involved"). For example, advertising bans cannot be imposed to protect the ethical standards of a profession. See, *e.g.*, *Bates*, 433 U.S. at 378 ("Restraints on advertising * * * are an ineffective way of deterring shoddy work."). See also *Rubin* v. *Coors Brewing Co.*, 514 U.S. 476, 491 (1995) (prohibition against including alcohol content on beer labels was "more extensive than necessary" because government had alternative options to advance its interest "in a manner less intrusive to respondent's First Amendment rights").

That the government's larger goal is to preserve the public's health and welfare does not justify the suppression of valuable information and market regulation through consumer ignorance. This approach was soundly rejected in *Virginia State Bd. of Pharmacy*, the first case to recognize First Amendment protection for commercial speech:

> There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests only if they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them. * * * It is precisely this kind of choice, between the dangers of suppressing information and the dangers of its misuse * * *, that the First Amendment makes for us.[81]

By limiting information, and keeping consumers and physicians in the dark about drugs that can be made available through compounding, Section 503A prevents consumers from learning about and receiving beneficial – or even essential – drug therapies. Causing patients who cannot use mass-produced pharmaceutical products (*e.g.*, because they have allergies, cannot swallow, or cannot keep a medicine down) to be unaware of concrete solutions to their medication needs is a far greater menace to public health and well being than having truthful information regarding these options available in the marketplace.

CONCLUSION

The judgment of the court of appeals should be affirmed.

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[81] 425 U.S. at 770.

Respectfully submitted.

JOHN M. RECTOR
General Counsel
National Community
Pharmacists Association
205 Daingerfield Road
Alexandria, VA 22314
(703) 683-8200

KENNETH S. GELLER*
BRITTON B. GUERRINA
Mayer, Brown & Platt
1909 K Street, N.W.
Washington, D.C. 20006
(202) 263-3000

* *Counsel of Record*

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